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In the Supreme Court

OF THE

United States

OCTOBER TERM, 1972

No. 72-1016

CHIP STEAK CO., INC., VAO L. CHENEY, MILLER PACKING CO., FRANK DE BENEDETTI AND WESTERN STATES MEAT PACKERS ASSOCIATION, L. BLAIN LILJENQUIST,
Petitioners

vs.

CARL L. BUTZ, SECRETARY OF AGRICULTURE, J. C. LEIGHTY, DIRECTOR OF TECHNICAL SERVICE DIVISION, M. E. CHRISTOPHERSON, DIRECTOR OF WESTERN MEAT INSPECTION, *Respondents*

PETITION FOR A WRIT OF CERTIORARI to the United States Court of Appeals for the Ninth Circuit

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Table of Contents

	Page
Citations to Opinions Below	2
Jurisdiction	2
Questions Presented	2
Statutes and Regulations Involved	3
Statement of the Case	3
Argument on Reasons for Granting the Writ	10
(1) Two important questions of federal law have not been decided and thus should be settled by this Court	10
(2) The lower courts have sanctioned major departures from the accepted and usual course of due process in an administrative rule-making proceeding	15
(3) The lower courts have sustained contradictory interpretations of identical statutory provisions contained in the Federal Food, Drug and Cosmetic Act and in the Meat Inspection Act	18
Conclusion	21

Index to Appendices

	Page
A. U.S. Department of Agriculture Memorandum stated July 31, 1970	
B. Decision of the U.S. District Court	
C. Court reporter's transcript of the oral hearing wherein the District Court denied petitioners' motion to amend findings and memorandum of decision	
D. Per Curiam opinion of the U.S. Court of Appeals for Ninth Circuit	
E. Petition for a rehearing in the U.S. Court of Appeals	
F. Order denying petition for a rehearing	
G. Text of relevant statutes and regulations	

Table of Authorities Cited

Cases

Pages

Bentex Pharmaceutical, Inc. v. Richardson (C.A. 4, 1972) 463 F. 2d 363, cert. granted Jan. 8, 1973 11

Chip Steak Co. v. Hardin, 332 F. Supp. 1084 (N.D. Cal. 1971) 2

Interstate Commerce Com. v. Louisville and Nashville R.R. Co. (1913) 227 U.S. 88 15

Morgan v. United States (1936) 298 U.S. 468 15
Morgan v. United States (1937) 304 U.S. 1 15

Schuck v. Butz, Civil No. 864-72 (D.D.C. 1972) appeal pending, Docket No. 72-1973 (3rd Cir.) 17

Willapoint Oyster, Inc. v. Ewing et al. (CA-9, 1949) 174 F. 2d 676, cert. den. 338 U.S. 860 20

Congressional Reports

House Report:
No. 13254 (85th Congress, 2nd Session) 12
No. 92-1338 (92nd Congress, 2nd Session, Aug. 15, 1972) pp. 3 and 6 4
No. 92-1338 (1972) pp. 20-26 17

Senate Report, No. 2422 12

Regulations

9 CFR:
No. 318.7(a) 7, 9, 17, 22
No. 318.7(a)(1)(2)(e) 2, 11
No. 318.7(a) 3
No. 318.7(c) 3, 15
No. 318.7(d)(2) 3, 7, 8, 9, 10, 14, 15, 22
No. 348(f)(2) 14

21 CFR, No. 212.101(d)(2) 6, 16, 17

34 F.R.:
Nos. 13194-13255 9
No. 13229 15
No. 15362 .....9, 15, 16

BLEED THROUGH POOR COPY

Pages

35 F.R.:
No. 15553 16
No. 15588 7
No. 15592 ..... 7, 15

36 F.R., No. 20546 18

37 F.R., No. 25705 18

Statutes

Administrative Procedure Act, 20 Stat. 392, 5 USC 702, Sec. 10 10

21 USC:
Section 342(b) 3, 19, 20
Section 348 ..... 8, 14
Section 348(e)(f) 8
Section 348(g)(3) 14
Section 348(h) 3, 8, 12, 23
Section 409(h) 3
Section 601(m)(2)(C) 2, 5, 7, 12
Section 601(m)(2)(D) 2, 8, 11, 23
Section 601(m)(8) 3, 18, 20

28 U.S.C., Section 1254(1) 2

Texts

The Superlawyers, Joseph C. Goulden, Waybright and Talley, New York, 1972, pp. 203-204 ..... 21, 22

Comment from Ralph Nader's Center for Study of Responsible Law, submitted on Dec. 21, 1969, on proposed Meat Inspection Regulations (34 F.R. 13194-13255) p. 4, III Meat Inspection 18

The New York Times, Oct. 8, 1971, Sec. I, p. 25, bottom cols. 1 and 2: U.S. Indicts 40 (U.S.D.A.) Meat Inspectors on Charge of Accepting Bribes 22

Pages

Science, Vol. 179, Jan. 5, 1973, p. 45-47 11

Sixth Report of the Joint FAO/WHO Expert Committee on Food Additives: Evaluation of the Toxicity of a Number of Antimicrobials and Antioxidants, FAO Nutrition Meetings Report Series No. 31 and World Health Organization's Technical Report, Series No. 228, Geneva, 1962. Monograph, pp. 90-92 6

United States Code and Cong. Adm. News, 90th Cong., 1st Sess., Vol. 2, p. 2203 19

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PETITION FOR A WRIT OF CERTIORARI
to the United States Court of Appeals for the Ninth Circuit

Petitioners pray that a writ of certiorari issue to the United States Court of Appeals for Ninth Circuit, in the above-entitled case.

CITATIONS TO OPINIONS BELOW

The decision of the District Court is reported in *Chip Steak Co. v. Hardin,* 332 F.Supp. 1084 (N.D. Cal. 1971) and is printed in Appendix B hereto. The per curiam opinion of the Court of Appeals for the Ninth Circuit is reported in 367 F.2d 481, and is printed in Appendix D hereto.

JURISDICTION

The judgment of the Court of Appeals was entered on October 31, 1972. Rehearing was denied on November 20, 1972. The jurisdiction of this Court is invoked under 28 U.S.C. Section 1254(1).

QUESTIONS PRESENTED

Petitioners seek declaratory relief regarding the following questions of federal law to determine the Secretary of Agriculture's scope of statutory authority in approving and restricting chemical substances in meat products:

1. Whether regulations 9 CFR 318.7(a)(1)(2) and (c) are unconstitutional and void because the Secretary of Agriculture lacks the statutory authority to approve food aditives for use in meat products under 21 USC 601(m)(2)(D) of the Meat Inspection Act as amended.

2. Whether the Secretary of Agriculture's promulgation of regulations prohibiting food aditives in meat

products must be accomplished in accordance with specific statutory procedures required by 21 USC 348 (h) of the Food Additive Amendment.

3. Whether identical statutory provisions contained in the Federal Food, Drug and Cosmetic Act and in the Meat Inspection Act, should be uniformly applied in the regulation of food additives.

STATUTES AND REGULATIONS INVOLVED

The statutory provisions involved are Section 1(m)(2)(C), (D) and 1(m)(8) of the Wholesome Meat Act of 1967, 81 Stat. 584, amending the Meat Inspection Act, 21 USC 601(m)(2)(C), (D) and 601(m)(8); Section 402(b) of the Food, Drug and Cosmetic Act of 1938, 52 Stat. 1046, 21 USC 342(b); and Section 409(h) of the Food Additive Amendment of 1958, 72 Stat. 1785, 21 USC 348(h). The regulations involved are 9 CFR 318.7(a), (c) and 9 CFR 318.7(d)(2). They are printed in Appendix G.

STATEMENT OF THE CASE

A recent congressional report on the regulation of food additives specified that the Wholesome Meat Act "incorporated the protective coverage of the Food Additive Amendment" by reference into the Meat Inspection Act. The report outlined the respective jurisdiction of the Secretary of Health, Education and Welfare through the Food and Drug Administration (FDA) and of the Secretary of Agriculture through

the Animal and Plant Health Inspection Service (APHIS) as follows:

> "FDA has the responsibility for determining the safety of all food additives, and for publishing regulations approving additive uses and establishing limitations on the amounts of aditives that may be used for given purposes. FDA also has the responsibility to monitor the Nation's food supply, with the exception of meat, poultry and egg products, to assure the safety of food additive uses. This involves the inspection of establishments and the sampling and analysis of marketed foods to determine the quantity of aditives present.
>
> "While *FDA must evaluate food aditives for use in meat,* poultry and egg products, APHIS has the responsibility for enforcing quantitative restrictions and proper use of additives in these products. APHIS exercises this responsibility through the continuous inspection of meat, poultry and egg products establishments." [Emphasis added.]
>
> House Report No. 92-1338, on "Regulation of Food Additives—Nitrite and Nitrates" by the Committee on Government Operations (92 Cong. 2d Sess., August 15, 1972) pages 3 and 6.

This statement summarizes Congress' intention as to how food additives are to be regulated in the United States. But the Secretary of Agriculture is approving and disapproving chemical substances in meat products contrary to the provisions of its Congressional mandate. And the lower courts are allowing this circumvention of the law to continue. The present re-

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quest for writ of certiorari is an attempt to settle the question as to whether the provisions of the Wholesome Meat Act and the Food Additive Amendment mean what they say, and whether the United States Department of Agriculture is to be held to them.

The Meat Inspection Act as amended by the Wholesome Meat Act gives the USDA one method only of modifying the list of safe food additives established by the FDA. That method is to prohibit specific approved additives for use in meat products through proper promulgation of regulations as given in 21 USC 601(m)(2)(C) and (D):

> "(m) The term 'adulterated' shall apply to any . . . meat food product under one or more of the following circumstances . . .
>
> (2) (C) If it bears or contains any food additive which is unsafe within the meaning of Section 348 [Food Additive Amendment administered by the Secretary of H.E.W.] of this title.
>
> (D) . . . *Provided,* that an article which is not adulterated under Clause (B), (C) or (D) shall nevertheless be deemed adulterated if the use of pesticide chemical, food additive, or color fixative in or on such article is *prohibited by regulations of the Secretary* [*of Agriculture*] in this subchapter." (Emphasis added.)

This Court is asked to consider the ways in which the USDA has bypassed or shortcut this law.

Prior to the bringing of the original complaint in this action on August 28, 1968, the Secretary of Agri-

culture routinely regulated the use of food additives in meat by issuing "Technical Service Notices" rather than promulgating regulations. After the filing of the original complaint, the Secretary discontinued this practice and fell back on a second maneuver, that of prohibiting in meat products certain additives already approved by the FDA by disapproving individual labels which declared the presence of those additives. The petitioners protested this second practice via an "Amended Complaint for Declaratory Judgment and Injunction to Restrain Enforcement of an Illegal Administrative Practice" filed March 6, 1969. The petitioners chose potassium sorbate as a test additive because the sorbates are universally recognized among scientists as safe[1] and are approved by the FDA for use as a preservative in food through regulation 21 CFR 212.101(d)(2).

Once again, the Secretary of Agriculture sought to head off the complaint, this time by issuing two regu-

[1]Sixth Report of the Joint FAO/WHO Expert Committee on Food Additives: Evaluation of the Toxicity of a Number of Antimicrobials and Antioxidants, FAO Nutrition Meetings Report Series No. 31 and World Health Organization's Technical Report Series No. 228, Geneva, 1962.

These United Nations organizations classified sorbic acid (which would include its salts—potassium sorbate) as naturally occurring substances and very safe (page 12). The monograph on sorbic acid describes its use as an antimicrobial preservative in foods; it is an active agent against mold and yeast and to a lesser degree against bacteria. The monograph further states that sorbic acid inhibits the dehydrogenase in mold and yeast but it is impossible to give sufficient sorbic acid to inhibit the dehydrogenase enzyme system in man or any other animal body. In addition, the monograph states sorbic acid is a relatively simple compound that appears to be readily metabolized in the animal body, and, in the presence of sufficient metabolizable carbohydrates, the end-products are carbon dioxide and water. Monograph on pages 90-92.

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lations published in final form on October 3, 1970. The first was a blank check empowering USDA officials to approve or disapprove additives at their own discretion 9 CFR 318.7(a) [35 F.R. 15588]:

> No chemical substance may be used in the preparation of any [meat] products unless it is *approved* in this part or Part 319 of this subchapter or *by the Administrator in specific cases.* (Emphasis added)

The second regulation specifically banned the use of sorbates among other aditives in meat products 9 CFR 318.7(d)(2) [35 F.R. 15592]:

> No substance may be used in or on any products if it conceals damage or inferiority or makes the product appear to be better or of greater value than it is. Therefore: . . .
>
> (2) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid may not be used in cooked sausage or any other product . . .

The scope of the problem had expanded. In addition to using extra-legal methods for regulating additives, the USDA was now using rulemaking but in two fundamentally improper ways. In the first place, the content of 9 CFR 318.7(a) is manifestly contrary to 21 USC 601(m)(2)(C) and (D) with its specification that the Secretary of Agriculture can only prohibit FDA-approved aditives for use in meat rather than approve additives as safe himself. In the second place, the agency did not promulgate regulation 318.7(d)(2) according to the procedure specified for it by lawmakers. When the Secretary of Agriculture prohibits

or restricts HEW-approved additives by making regulations under the Meat Inspection Act as amended (21 USC 601(m)(2)(D)), he is repealing or amending a regulation promulgated under the Food Additive Amendment (21 USC 348). Thus, the manner in which the Secretary of Agriculture makes regulations prohibiting specific food additives must conform to 21 USC 348(h):

> "The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedures shall conform to the procedure provided in this section [Food Additive Amendment] for the promulgation of such regulations."[2]

9 CFR 318.7(d)(2) was issued in final form without the statutorily-mandated prior notice, so that no opportunity was given to the concerned parties to pre-

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[2]The complete procedure referred to is found in 21 USC 348(e)-(f), excerpts of which are as follows:

(d) The Secretary may at any time, upon his own initiative propose the issuance of a regulation prescribing with respect to any particular use of a food additive the conditions under which such additive may be used and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

(f) (1) Within thirty days . . . any person adversely affected by such an order may file objections. . . . The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purposes of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

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sent scientific evidence concerning the validity of use of sorbates in meat.

What has been the reaction of the courts to these alleged acts of the USDA?

On December 23, 1969, the District Court ruled against plaintiff on his Amended Complaint for Declaratory Judgment and Injunction to Restrain Enforcement of an Illegal Administrative Practice on the grounds that, after the filing of the amended complaint, the USDA had published proposed regulations in the Federal Register, August 15, 1969 (34 F.R. 13194-13255) and thus was in the process of revising its policy of regulating additives via Technical Service Notices and label disapprovals. Plaintiffs objected that the content of the proposed regulations was not in accord with the law, but the District Court on March 6, 1970, denied plaintiffs' motion for summary judgment as prematurely brought because the USDA had not issued their final regulations.

After the final regulations were issued, cross-motions for summary judgment were submitted to the District Court on February 12, 1971. On October 20, 1971, the District Court entered judgment in favor of the Secretary of Agriculture. The Court did not rule regarding the legality of regulation 318.7(a). Its decision on regulation 318.7(d)(2) was based upon a document outside the administrative record of the rule-making proceedings (See Appendix A dated July 31, 1970; administrative record was closed on December 12, 1969 (34 F.R. 15362)). The Secretary of Agriculture had no data in the official administrative rec-

ord supporting the prohibition of the use of sorbates in meat products.

On November 29, 1971, the District Court denied appellants' Motion to Amend the Findings and memorandum of decision. At the hearing on this motion petitioners again submitted written citations to the Federal Register as evidence of alleged improper and faulty rule-making procedures in promulgating food additive regulations for meat food products, but the District Court declined to take judicial notice. (See Appendix C.)

On October 31, 1972, the Court of Appeal affirmed the District Court. It mentioned one issue only, that of the validity of regulation 318.7(d)(2). It upheld the regulation with a single sentence "We agree with the District Court that the asserted deficiencies in the departments' rule-making procedures afford no basis for attacking the regulation." (See Appendix D.)

On November 28, 1972, the Court of Appeal denied appellants' petition for a rehearing, once again ignoring the basic questions presented in this writ. (See Appendix E.)

ARGUMENT ON REASONS FOR GRANTING WRIT

1. TWO IMPORTANT QUESTIONS OF FEDERAL LAW HAVE NOT BEEN DECIDED AND THUS SHOULD BE SETTLED BY THIS COURT.

Section 10 of Administrative Procedure Act, 20 Stat. 392, 5 USC 702, provides:

> A person suffering legal wrong because of agency action or adversely affected or aggrieved by agen-

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> cy action within the meaning of a relevant statute, is entitled to judicial review thereof.

Case law underlines this principle, as in *Bentex Pharmaceutical, Inc. v. Richardson* (C.A. 4, 1972) 463 F. 2d 363, 371-372, certiorari granted, January 8, 1973.

The petitioners plead that they have not been accorded the judicial review to which they are entitled on two federal questions; neither of the lower courts have made rulings on them (see Appendix E). Thus, for the present Court the petitioners briefly summarize their arguments regarding these two federal questions of law:

(a) Whether regulations 9 CFR 318.7(a)(1)(2) and (c) are unconstitutional and void because the Secretary of Agriculture lacks the statutory authority to approve food additives for use in meat products under 21 USC 601(m)(2)(D) of the Meat Inspection Act as amended.

The USDA is obliged to utilize the list of approved food additives developed by the FDA rather than to draw up its own list. The practical reasons behind this obligation are: (1) the FDA has the proper resources and machinery to determine which chemical substances are safe and of worth as potential additives, whereas the USDA does not[3]; and (2) inevitably,

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[3]See *Science*, Vol. 179, January 5, 1973, pages 45-47, article entitled: Agriculture: National Academy of Science Panel Charges Inept Management, Poor Research—". . . The Survey faults the quality of agricultural research right across the board, ranging from poor administrative leadership in the U.S.D.A., to misallocation of resources for research, neglect of basic sciences, and the low quality of science and scientists both in the U.S.D.A. and at state supported research institutes."

wasteful duplication of effort, confusion and unequal application of the law result when the USDA sets about to compete with the FDA and draw up its own list. The legal reason why the USDA is obliged to utilize the same list as the FDA is found, as we have seen, in 21 USC 601(m)(2)(C) and (D). These same sections give the USDA the means by regulations to modify the FDA's list regarding application to meat products, when the USDA can produce valid reasons for doing so.

(b) Whether the Secretary of Agriculture's promulgation of regulations prohibiting food additives in meat products must be accomplished in accordance with specific statutory procedures required by 21 USC 348(h) of the Food Additive Amendment.

The Secretary of Agriculture's promulgation of regulations prohibiting or restricting food additives in meat products must be accomplished in accordance with specific statutory procedures required by 21 USC 348(h) of the Food Additive Amendment.

Senate Report No. 2422, which accompanied the Food Additive Amendment (H.R. 13254, 85th Congress, 2nd Session), stated in part as follows:

> "Ever since the Congress began delegating regulatory functions to administrative agencies of the Government there has been disagreement among lawyers as to the fairness of the procedures under which the agencies operate. In 1946, the Administrative Procedure Act was passed in an effort to formalize the day-to-day rulemaking and regulatory procedures of Government agencies. The 1946 act provides that unless the findings of fact upon which administrative orders are based are

supported by 'substantial evidence' a Federal Court of Appeals can reverse the order of the administrative agency. Court decisions have required that an administrative agency must give consideration to the entire record, including contradictory evidence, when it determines facts.

Manufacturers of food and food additives have manifested concern that under an administrative type of control over the use of food additives, such as is provided by H.R. 13254, it would be possible for the institutional decision of the Secretary of Health, Education and Welfare to be based, for example, more upon the personal convictions of scientists employed by the Food and Drug Administration regarding the safety of an additive than upon the inferences fairly to be drawn from the scientific evidence of record. H.R. 13254 provides that orders regarding the use of food additives must 'be based upon a fair evaluation of the entire record.' The committee has endeavored to prescribe a new statutory criterion requiring that a high standard of fairness be observed in administrative rulemaking under this bill. Personal attitudes or preferences of administrative officials could not prevail on the basis of being supported by substantial evidence picked from the record without regard to other evidence of probative value in the record. The United States Court of Appeals will be able to enforce this high standard by determining whether the Secretary of Health, Education and Welfare has given appropriate consideration to the inferences which should fairly be drawn from all of the evidence of Record."

(U.S. Code Cong. and Admin. News, 85th Congress, 2d Sess. Vol. 3, pp. 5307-8).

Congress certainly was equally concerned that the "personal attitudes or preferences of administrative officials could not prevail" in the U.S. Department of Agriculture. So Congress' legislative desire is clear in establishing statutory safeguards against arbitrary administrative action. The agencies are not to act according to the convictions of those officials handling individual cases, but rather to make rules according to the "high standard of fairness" given in the Food Additive Amendment, 21 USC 348.

In dealing with regulation 318.7(d)(2) the Court of Appeals ignored their specific charge contained in 21 USC 348(g)(3) which Congress wrote due to the foregoing considerations:

> The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f)(2) of this section.

348(f)(2) states:

> Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

The order of the Secretary of Agriculture establishing regulation 318.7(d)(2) should have been overturned because it was not based "upon a fair evaluation of the entire record. . . ."

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2. THE LOWER COURTS HAVE SANCTIONED MAJOR DEPARTURES FROM THE ACCEPTED AND USUAL COURSE OF DUE PROCESS IN ADMINISTRATIVE RULE-MAKING PROCEEDINGS.

First, there was no notice of proposed regulation stating *why* sorbates were to be prohibited in meat products. It is a fact that 9 CFR 318.7(d)(2) was not published as a proposed regulation in the Federal Register (34 F.R. 13229). It was published for the first time in the Federal Register as a final regulation (35 F.R. 15592). The District Court concluded there was implied notice, since sorbates were not included on the so-called "permitted list" of proposed regulation 9 CFR 318.7(c). Petitioner strongly disagrees since meaningful participation in rule-making requires knowledge of the content and rationale of the proposed regulation. Moreover, *Morgan v. United States* (1937) 304 U.S. 1, 14-15, 18-19, *Morgan v. United States* (1936) 298 U.S. 468, 479-481, and *Interstate Commerce Com. v. Louisville and Nashville R.R. Co.* (1913) 227 U.S. 88, 91, all hold that a statute calling for the adoption of regulations upon public notice implies that the evidence supporting the proposed regulation be disclosed and made part of an administrative record in order to provide opportunity for refutation.

Secondly, there was no administrative record to support a regulation prohibiting sorbates in meat products. It is a fact that the rule-making hearing on the group of proposed regulations (not including, as we have seen, 318.7(d)(2)), closed on December 12, 1969 (34 F.R. 15362) and there were no comments relating to sorbates in the administrative record ex-

cept industry's comments that sorbates were approved for use as a food preservative in meat products by regulation 21 CFR 212.101(d)(2) under the Food Additive Amendment. The Secretary of Agriculture published his final regulations on October 3, 1970, and stated his considerations for prohibiting sorbates in meat products (35 Fed. Reg. 15553). The Secretary's sole "consideration" quoted almost word for word from a memorandum prepared by USDA employee Ralph W. Johnston and dated July 31, 1970 (See Appendix A). The District Court refused to take judicial notice that this government memorandum was not part of the administrative record (See Appendix C) because the memorandum was prepared six months after the hearing closing date for all comments (34 F.R. 15362).

The scientific community would have refuted Mr. Johnston's erroneous memorandum that sorbates are unsafe in meat food products if proper notice had been given in a proposed regulation and a realistic opportunity to be heard had been provided. For example, Professor Reese Vaughn's scientific article was specifically cited in a handwritten note on said Johnston memorandum as the basis for the rejection of sorbates in meat food products (See Appendix A). Professor Vaughn in his affidavit to the District Court stated:

> I do not believe the use of sorbic acid or sorbates in meat should have been rejected on the basis of data developed by Emard and Vaughn (specific reference in Johnston's memorandum) and York and Vaughn . . .

Professor Vaughn along with Dr. George York went on to state they believed sorbates should be used in cooked sausage products to prevent mold and speed up destruction of salmonella and staphylococcus bacteria, which can cause typhoid fever and other food infection in man.

As the situation now stands, the issue of why sorbates should not be allowed in meat products remained unresolved. The sorbates, with their very decided benefits of reducing the chances of contracting salmonellosis or other food infections from eating meat, are deemed safe by regulations promulgated under the Food Additive Amendment. (21 CFR 212. 101(d)(2).) The Secretary of Agriculture has given no reasons in his notice to contradict this finding by the Commissioner of the Food and Drug Administration. And the Courts, by ignoring their charge to hold the USDA to proper rule-making procedures, have reinforced that agency in practices which make industry's life difficult and the consumer's life, at times, dangerous.[4]

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[4]Consumer groups as well as the meat industry are concerned about the protective coverage of the Food Additive Amendment in regulating food additives in meat products. Ralph Nader's group has questioned the approval by the Secretary of Agriculture of nitrates and nitrites in meat products (*Schuck v. Butz*, Civil No. 864-72 (D.D.C. 1972) appeal pending, Docket No. 72-1973 (3rd Cir.).)

See also House Report No. 92-1338 (1972) supra, pages 20-26. The Committee's findings and conclusions allege that nitrites and nitrates in food pose a potential danger to public health.

In addition, consumer groups have strongly objected to regulations, such as 9 CFR 318.7(a) as follows:

> "Throughout the proposed and existing [meat inspection] regulations, procedures are established with no published guidelines and standards are set which are so vague as to

3. THE LOWER COURTS HAVE SUSTAINED CONTRADICTORY INTERPRETATIONS OF IDENTICAL STATUTORY PROVISIONS CONTAINED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND IN THE MEAT INSPECTION ACT.

Rather than giving credence to prestigious scientists and scientific bodies in coming to a decision on a scientific matter,[5] the District Court concluded that the USDA was right to ban sorbates in meat under 21 USC 601(m)(8) because they made a meat product "appear better or of a greater value than it is." The latter is a quote from the Meat Inspection Act which reads as follows (21 USC 601(m)(8)):

> (m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

---

allow almost complete discretion by the enforcing officers. The result must be a lack of uniformity in enforcement, unpredictability of enforcement, and lack of legal basis for enforcement. 'The greatest and most frequent injustice occurs at the discretion end of the scale, where rules and principles provide little or no guidance, where emotions of deciding officers may affect what they do, where political or other favoritism may . . . influence decisions, and where the imperfections of human nature are often reflected in the choices made.' Kenneth Culp Davis, Discretionary Justice, page No. v (1969)."

Comment from Ralph Nader's Center for Study of Responsible Law, submitted on December 21, 1969, on proposed Meat Inspection Regulations (34 F.R. 13194-13255) page 4, III Meat Inspection. (Appellee's Exhibit 1).

[5]The lower courts were informed that the Food and Drug Administration is presently reviewing its permitted list of good additives with the National Academy of Sciences—National Research Council. (36 F.R. 20546 entitled Industry Survey of Production and Use of GRAS Substances) During the present review, the FDA Commissioner has found no reason to remove the sorbates from its legal permitted list or restrict the use of sorbates as preservatives in meat products. (37 F.R. 25705 entitled "GRAS and Food Additive Status Procedures")

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> (8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength; or make it appear better or of greater value than it is;

This provision is a word-for-word quote of a provision in the Federal Food Drug and Cosmetic Act (21 USC 342(b)), for reasons explained in the legislative history of the Wholesome Meat Act.

> The Secretary of Agriculture and the Secretary of Health, Education and Welfare, would thus have concurrent jurisdiction under the Meat Inspection Act and the Federal Food, Drug and Cosmetic Act over meats and meat food products becoming adulterated or misbranded after inspection. *Since essentially the same criteria should be applied in determining wholesomeness* and branding, whether before or after inspection, *the bill would substitute the terminology used in the Federal Food, Drug and Cosmetic Act for that currently used in the Meat Inspection Act to describe adulteration* and misbranding. (U.S. Code and Cong. Adm. News, 90th Cong., 1st Session, Vol. 2 at p. 2203) (Emphasis added.)

In reading the foregoing an obvious legal question arises regarding the District Court's decision. Since the sorbates have the same effect—inhibition of mold and destruction of some kinds of bacteria—on all

food products, why should the criterion of making a product "appear better or of a greater value than it is" ban sorbates under the Wholesome Meat Act as administered by the USDA but not under the Food Additive Amendment as administered by the FDA?

Statutes in *pari materia* should be construed together and reconciled so as to uphold the same reasonable interpretation. *Willapoint Oyster, Inc. v. Ewing et al.* (CA-9, 1949) 174 F.2d 676 at 686 certiorari denied, 338 U.S. 860. Thus interpretation of phrases or sentences in 21 USC 342(b) should control interpretation of virtually identical expressions in 21 USC 601(m)(8).

If the District Court's mistaken interpretation of 21 USC 601(m)(8) continues to prevail, then the food industry will be faced with the following paradox. 21 USC 342(b) does not apply to sorbates because they have been declared by the Commissioner of the Food and Drug Administration's regulations (on the basis of scientific investigation and procedural guidelines required by the Food Additive Amendment) to be safe and effective for use in food products. However, under the identical provision contained in 21 USC 601(m)(8) sorbates are prohibited in meat products on the basis of "personal attitudes and preferences of administrative officials", which Congress said "could not prevail."

CONCLUSION

A cynical but prevalent viewpoint among attorneys dealing with food law is expressed in *The Superlawyers*, Joseph C. Goulden, Waybright and Talley, New York, 1972, pages 203-204:

> "Most industry lawyers—including [Thomas] Austern—don't feel the courts are capable of monitoring agency processes. The courts are loath to overturn an agency's interpretation of its controlling statute; the courts are not physically able to read the massive formal record that accompanies each appeal; the courts are convinced that agencies have 'expertise'. And, further, as Austern told a group of food-law specialists in 1969:
>
> > "Somehow during the course of almost every judicial hearing, someone mentions 'cancer.' The judge then remembers his mother-in-law, who, at the age of 108, died of cancer. He grabs his belly, and flying out of court goes that purveyor of those noxious, contaminated, filthy, unsafe, hazardous and defiled foods. If the product also happens to contain a chemical, that even more promptly ends the court argument."

The petitioner's experiences in bringing this case through the courts for the past four years unfortunately bear out the attitude that it is exceedingly difficult to obtain objective judicial review where food regulations are concerned. While understanding the reasons why this is so, the petitioners can only point to the sad consequences of the courts' reluctance to

deal with the matter. Quoting again from *The Superlawyers*, p. 204:

> "Austern's laments about the plight of the corporations must not be taken too seriously. A skilled Washington lawyer need not accept an unfavorable staff-level decision. He can undercut the bureaucracy by appealing to a higher official within the agency, by invoking Congressional pressure, by going to a friendly court . . ."

The extreme reluctance of the court to act as watchdogs on government food-regulating agencies encourages industries and consumers with legitimate grievances to bypass the courts—at best to try to pressure, to deal and to manipulate the bureaucracy and at worst to try to bribe individual members thereof.[6] Our system of justice and the public are the losers.

In the present instance the Secretary of Agriculture has overruled statutory protection for the meat industry and consumers provided by Congress in the Food Additive Amendment, by promulgating regulation 9 C.F.R. 318.7(a). The Secretary has denied the public of an additive rendering meat products more safe and denied the meat industry procedural due process in rule-making by the manner in which he promulgated 9 C.F.R. 318.7(d)(2).

The basic relief sought by petitioners is that the Secretary of Agriculture be confined to restricting food additives in meat products by promulgating

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[6]The New York Times, October 8, 1971, Section 1, page 25, bottom columns 1 and 2: U.S. Indicts 40 [U.S.D.A.] Meat Inspectors on Charge of Accepting Bribes.

regulations within the procedural guidelines of the Food Additive Amendment as a matter of law, 21 USC 601(m)(2)(D) and 348(h).

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Dated, San Francisco, California,
January 16, 1973.

Respectfully submitted,
GEORGE ALEXANDER McKRAY,
Attorney for Petitioners.

(Appendices Follow)

UNITED STATES DEPARTMENT OF AGRICULTURE

CONSUMER AND MARKETING SERVICE

CONSUMER PROTECTION PROGRAMS

Appendix A

WASHINGTON, D.C. 20250

July 31, 1970

bject: The Use of Sorbates in Formulas for Cooked Sausage Products

To: Jack C. Leighty, Director
Technical Services Division

rough: R. Paul Elliott, Chief
Laboratory Branch
Technical Services Division

Salts of sorbic acid have been approved as a food additive for the purpose of preventing the growth of yeasts and molds. Sorbic acid is normally used in amounts of 0.01 to 0.1 percent in foods such as citrus products, pickles, salads and candies. It appears to be most effective at a pH of 5 or below.

Mold and bacterial slime develop on the surface of sausage products held for long periods under good refrigeration or for shorter periods at higher temperatures. The appearance of mold serves as a warning signal to the consumer to discard the product.

Sorbates or sorbic acid have been permitted for surface treatment of some semi-dry or dry sausage products. In these products, bacterial growth is not a concern due to the low water activity and pH. They are stable for long periods except for slow mold growth on the surfaces. In this case, sorbates are clearly helpful.

In non-dried sausage emulsions, the pH range is 5.9 to 6.2. At this level, the effectiveness of sorbates is reduced. The presence of sorbates throughout the emulsion would not appear to be necessary since mold development is a surface defect.

The presence of sorbates in subsurface sausage tissues could result in a change in the bacterial flora of the product. This change, theoretically, could result in an increase in the health hazard of such products. Since 1954, sorbic acid has been used in laboratory culture media to facilitate the growth and isolation of clostridia. Sorbic acid permits the growth of clostridia while selectively inhibiting the development of aerobic bacteria. Sorbic acid at a concentration of 0.12 percent in broth media adjusted to pH 5.5 has been found to selectively inhibit aerobic bacteria and to permit luxuriant growth of clostridia. These conditions are similar to those that would exist in meat emulsions containing sorbates. Although sausage

products are refrigerated, the combination of extended shelf life, temperature abuse in distribution and a shift in bacterial flora could create a problem. Clostridium perfringens and Clostridium botulinum are the two organisms of health hazard concern.

I do not believe that this information has been considered in evaluating the addition of sorbates to meats and other neutral food products. This aspect of the situation should be considered by those who propose the use of sorbic acid in meat emulsions and regulatory officials.

Four reprints are attached to document the laboratory use of sorbic acid to selectively isolate clostridia.

→ This is not the case. Our rejection of sorbic in meat products in 1961 was based, in part, on data developed by Emard & Vaughn which showed the selective, bacterial functions and effects of sorbic acid. The use of parabens in meats was rejected for similar reasons. R.P.L.

Ralph W. Johnston

Ralph W. Johnston, Head
Microbiology Group
Laboratory Branch
Technical Services Division

Attachments

Appendix B

United States District Court
Northern District of California

No. 49834

Chip Steak Co., Inc., et al.,
Plaintiffs,
vs.
Clifford Hardin, etc., et al.,
Defendants.

[October 20, 1971]

MEMORANDUM OF DECISION

SWEIGERT, J.

This action, brought for declaratory and injunctive relief, is before the court on plaintiffs' and defendants' cross-motions for summary judgment.

Plaintiffs Chip Steak Co.; Vao L. Cheney, president of Chip Steak Co.; Western Meat Packers Association; and, L. Blaine Liljenquist, president of the Western Meat Packers Association, bring this action against Clifford Hardin, Secretary of Agriculture; J. C. Leighty, Director, Technical Services Division, Consumer and Marketing Service, United States Department of Agriculture ("U.S.D.A."); and, M. E. Christopherson, Director, Western District Meat Inspection, San Francisco, California.

Plaintiffs allege in their first amended complaint that the Technical Service Division, Consumer and Marketing Service of U.S.D.A. prohibits the use of certain food preservatives, specifically, calcium sorbate, sodium sorbate, potassium sorbate and sorbic acid, in the manufacturing and processing of certain meat food products, by its practice of *not* approving labels which declare the presence of said preservatives; that said practice is contrary to the provisions of the Wholesome Meat Act; that no scientific basis exists for prohibiting the use of these preservatives; that plaintiffs desire to use these chemical preservatives in their products and that continued enforcement of the above practice threatens great and irreparable damage to plaintiffs' property rights.

On the basis of the above allegations plaintiffs seek in their amended complaint a declaratory judgment "that an administrative practice of the United States Department of Agriculture is invalid in that it is contrary to the procedures of the Wholesome Meat Act of 1967"; an injunction against the enforcement of said administrative practice; and, an order directing U.S.D.A. to comply with statutory rule-making procedures.

Defendants deny the existence of the practice as alleged by plaintiffs but admit that U.S.D.A. is continuing to disapprove labels which declare that chemical preservatives are present such as to cause the product to be adulterated or misbranded.

In earlier stages of this action this court denied, without prejudice, plaintiffs' motion for declaratory

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relief (denied December 23, 1969) and plaintiffs' motion for summary judgment (denied March 6, 1970) as prematurely brought since at that time U.S.D.A. was conducting rule-making proceedings on the issue of food additives in meat products.

U.S.D.A. has since adopted a regulation, 9 C.F.R. 318.7(d)(2), pursuant to the Federal Meat Inspection Act of 1907, 34 Stat. 1260, as amended by the Wholesome Meat Act of 1967, Pub. L. 90-201, 81 Stat. 584, 21 U.S.C. 601, et seq. (Supp. 1971), which provides as follows:

> "(d) No substance may be used in or on any product if it conceals damage or inferiority or makes the product appear to be better or of greater value than it is.
>
> Therefore:
>
> . . .
>
> (2) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid may not be used in cooked sausage or any other product . . ."

The court now has before it plaintiffs' renewed motion for summary judgment which is, in effect, an attack on the validity of the above regulation.

Plaintiffs allege that the prohibited additives have been safely used in the past; that plaintiffs desire to use these additives in their products; and that to prohibit these additives would cause plaintiffs irreparable harm. We will assume that, if plaintiffs endeavor to market products bearing or containing the additives prohibited by the regulation, the products will be deemed "adulterated" by the Secretary of Ag-

riculture and that plaintiffs may be subject to adverse publicity, defense of condemnation charges and possible fines.

Since the promulgation of 9 C.F.R. 318.7(d)(2) clearly constitutes final agency action, plaintiffs' challenge of the regulation is "ripe" for adjudication under *Abbot Laboratories v. Gardner,* 387 U.S. 136 (1967).

Plaintiffs first contend that the Secretary of Agriculture, in promulgating 9 C.F.R. 318.7(d)(2) under the Federal Meat Inspection Act, as amended, supra, was required by law to follow the same formalized rule-making procedures as are made applicable to the Secretary of Health, Education and Welfare under 21 U.S.C. 348 (Food, Drug and Cosmetic Act), i.e., oral public hearings if requested by interested parties. The record indicates that plaintiffs demanded an oral hearing in the instant rule-making but that no such oral hearing was held. (See Documentary Record of Rule-Making Proceedings, filed January 8, 1971).

Since there are no rule-making requirements in the Meat Inspection Act, as amended, plaintiffs base their contention on the principle that the Federal Meat Inspection Act and the Food, Drug and Cosmetic Act must be read together when they deal with the same subject matter, i.e., food additives, citing the legislative history of the Federal Meat Inspection Act, as amended, (U.S. Code Cong. & Adm. News, 90th Cong., 1st Sess., vol. 2, at pp. 2194-95 (1967) and *Willapoint Oyster, Inc. v. Ewing,* 174 F.2d 676 (9th Cir. 1949).

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If Congress had intended that the Secretary of Agriculture's rule-making functions under the Federal Meat Inspection Act were to be bound by the procedures governing the Secretary of Health, Education and Welfare under the Food, Drug and Cosmetic Act, it would have expressly so provided. Plaintiffs have cited no provision in the Federal Meat Inspection Act, as amended, supra, wherein the procedural requirements of 21 U.S.C. 348 are made applicable to the Secretary of Agriculture. Nor does a review of the legislative history of the Act reveal such a Congressional intent. Absent such a provision, rule-making procedures would be governed by the Administrative Procedure Act, 5 U.S.C. 500 et seq.

Plaintiffs contend that they were entitled to a public oral hearing under the Administrative Procedure Act, 5 U.S.C. 553.

Plaintiffs are in error. 5 U.S.C. 553, in subsection (c), merely provides that, after having given notice of proposed rule-making, the agency must give "interested parties an opportunity to participate in the rule-making through submission of written data, views, or arguments with or without opportunity for oral presentation." (emphasis added). In the discretion of the Secretary of Agriculture, opportunity to submit written comments or materials sufficiently met the hearing requirement of the Act. See, *American Trucking Ass'n v. United States*, 344 U.S. 298, 319-20 (1952); *California Citizens Band Ass'n v. United States*, supra. The administrative record of the rule-

making proceedings here in question indicates that plaintiffs were given the opportunity to submit such written data and views as provided by the Act and that they in fact did so. (Record of Rule-Making Proceedings, filed January 8, 1971).

Plaintiffs next contend that U.S.D.A., in promulgating 9 C.F.R. 318.7(d)(2), failed to give proper notice of that regulation as required under Administrative Procedure Act, 5 U.S.C. 553, providing in pertinent part that:

> "(b) General notice of proposed rule making shall be published in the Federal Register. . . . The notice shall include—
>
> (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved. . . ."

On August 14, 1969, U.S.D.A. published a notice of a proposed regulation 9 C.F.R., Parts 301-321 (34 Fed. Reg. 155, pt.2 at pp. 13194-13255) which included a proposed regulation 318.7 providing in subsection (a) that: "No product shall contain any substance which would render it adulterated or which is not approved by the Administrator" of the Consumer or Marketing Service of U.S.D.A. (34 Fed. Reg. at p. 13225). The notice then set forth a detailed chart of numerous additives which would be acceptable for use in meat products under specified conditions; sorbates were not included in that chart (except that potassium sorbate was allowed for use in dry sausage). (Id., at pp. 13225-29).

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When regulation 9 C.F.R. 318.7 was finally adopted, subsection (a) read as follows:

> "(a)(1) No chemical substance may be used in the preparation of any product unless it is approved in this part or Part 319 of this subchapter or by the Administrator in specific cases.
>
> (2) No product shall bear or contain any substance which would render it adulterated or which is not approved in this part or Part 319 of this subchapter or by the Administrator in specific cases."

Subsection (c)(4) of the finally adopted regulation, containing the chart of "acceptable" food additives, remained unchanged as to sorbic acid and sorbates. Also, a new subsection (d)(2) which did not appear in the published notice, was included in the final regulation:

> "(d) No substance may be used in or on any product if it conceals damage or inferiority or makes the product appear to be better or of greater value than it is.
>
> Therefore:
>
> . . .
>
> (2) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid may not be used in cooked sausage or any other product. . . ."

Plaintiffs argue that the failure of U.S.D.A. to publish in the above notice the precise terms of 9 C.F.R. 318.7(d)(2), as finally adopted, deprived them of the notice required under 5 U.S.C. 553, supra.

It has been held, however, that the Administrative Procedure Act does not require that the precise text of a proposed regulation be set forth in the published notice thereof so long as the published notice is sufficient to give affected parties notice of the substance of the proposed agency action. See, *California Citizens Band Ass'n v. United States,* 375 F.2d 43 (9th Cir. 1967); *Willapoint Oysters v. Ewing,* 174 F.2d 676 (9th Cir. 1949).

We are of the opinion that the notice as published sufficiently indicated that calcium sorbate, potassium sorbate, sodium sorbate and sorbic acid, which were not included in the chart, were to be prohibited in cooked sausage under the new regulation.

It appeared in the notice that only those additives which at some future time might be approved by U.S.D.A. or which appeared in the chart of "acceptable" additives, were to be used in meat products. The absence of sorbates from that list was highlighted by the fact that potassium sorbate for use in dry sausage (as distinguished from cooked sausage) was included.

It further appears that plaintiffs themselves, in their communications to U.S.D.A., so regarded the notice since they complained about what they described as the proposed prohibition of potassium sorbate. (See, copy of plaintiffs' reply brief, received by U.S.D.A. September 10, 1969, appearing in the Documentary Record of Rule Making Proceedings, filed January 8, 1971).

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We conclude, therefore, that there is no merit to plaintiffs' contention that the published notice was insufficient.

Plaintiffs next contend that the Secretary of Agriculture, in promulgating regulations on the use of food additives in meat products is bound by 21 C.F.R. 121.101, a regulation promulgated by the Secretary of Health, Education and Welfare pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq., permitting the use of certain food additives set forth in a list of substances characterized as "generally recognized as safe" among them calcium sorbate, potassium sorbate, sodium sorbate and sorbic acid.

Plaintiffs again argue that the Food, Drug and Cosmetic Act and the Federal Meat Inspection Act, as amended, must be read together when they deal with the same subject matter. Plaintiffs also rely on 21 U.S.C. 607 (c) (2) (Federal Meat Inspection Act, as amended) which provides that definitions, standards of identity or composition and standards of fill under the Federal Meat Inspection Act shall not be inconsistent with standards established by the Secretary of Health, Education and Welfare under the Food, Drug and Cosmetic Act and further that the Secretary of Agriculture and the Secretary of Health, Education and Welfare shall confer to coordinate effective administration of both Acts.

It is clear, however, that Congress, in amending the Federal Meat Inspection Act of 1907, 34 Stat. 1260, by enacting the Wholesome Meat Act of 1967, Pub. L.

90-201, 81 Stat. 584, 21 U.S.C. 601, et seq. (Supp. 1971), intended to vest the Secretary of Agriculture with the power to pass regulations prohibiting or restricting the use of food additives *in meat products* notwithstanding the designation of such additives as "generally recognized as safe" in regulations promulgated by the Secretary of Health, Education and Welfare under the Food, Drug and Cosmetic Act.

Title 21 U.S.C. 601(m)(2)(C) of the Federal Meat Inspection Act, as amended, provides that a meat food product shall be deemed adulterated if it bears or contains any food additive which is unsafe within the meaning of the Food, Drug and Cosmetic Act.

That provision, however, is qualified by the following proviso:

> "*Provided,* That an article which is not adulterated under clause . . . (C) . . . shall nevertheless be deemed adulterated if use of the . . . food additive . . . is prohibited by regulations of the Secretary (of Agriculture) in establishments at which inspection is maintained. . . ."

The legislative history of the Federal Meat Inspection Act, as amended, supra, indiciates that by the above proviso Congress intended to "allow the Secretary of Agriculture to impose *more stringent restrictions for food additives* . . . in or on meat products subject to the new act than are imposed by the Secretary of Health, Education and Welfare under the Federal Food, Drug and Cosmetic Act." (U.S. Code Cong. & Adm. News, 90th Cong., 1st Sess., vol. 2 at p. 2195 (1967) (emphasis added)).

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Further, an Act of September 6, 1958, Pub. L. 85-929, 72 Stat. 1789, amending the Food, Drug and Cosmetic Act to empower the Secretary of Health, Education and Welfare to promulgate regulations on food additives, expressly provides in Section 7 as follows:

> "Nothing in this Act (Federal Food, Drug and Cosmetic Act) shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the . . . Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U.S.C. 71 and the following)."

Plaintiffs finally contend that there exists no rational basis for 9 C.F.R. 318.7(d)(2).

Regulation 9 C.F.R. 318.7(d)(2) was promulgated by the Secretary of Agriculture pursuant to the authority granted in the proviso to 21 U.S.C. 601(m)(2)(D), discussed above, which provides that products will be considered to be adulterated if they contain food additives which are prohibited by regulations of the Secretary of Agriculture and 21 U.S.C. 601(m)(8) (Federal Meat Inspection Act, as amended) which provides that a meat product shall be considered "adulterated" if damage or inferiority has been concealed in any manner or if any substance has been added to it to make it appear better or of greater value than it actually is.

The prohibition of sorbates in the challenged regulation is expressly based on the ground that sorbates and sorbic acid are additives which conceal inferiority

and damage and make the product appear better than it actually is.

The Secretary of Agriculture in promulgating Regulation 9 C.F.R. 318.7(d)(2), made a finding to that effect in the following stated "considerations:"

> "Mold and bacterial slime develop on the surface of cooked sausages and similar products held for long periods under good refrigeration or for shorter periods at higher temperatures. The appearance of mold and other surface growth serves to alert consumers to the condition of the product. Sorbates are most effective moldicides and bactericides for products with high acidity, i.e., a pH of 5 or below. These chemicals are not effective in products such as cooked sausages since their pH ranges from 5.9 to 6.2. The presence of sorbates in subsurface sausage tissues results in changes in bacterial flora of the products. Sorbates have been demonstrated to inhibit selectively the development of aerobic bacteria and simultaneously permit the luxuriant growth of clostridium perfringes and clostridium botulinum which are organisms associated with serious health hazards. The use of sorbates for such products therefore conceals damage and inferiority because of bacterial action, and makes the products appear better and of greater value than they are in view of their decomposing condition." (35 Fed. Reg. No. 193, pt. II at p. 15553 (October 3, 1970))

These considerations are supported by materials set forth in the documentary record of the rule-making proceedings, specifically by the memorandum of Ralph W. Johnston, Head, Microbiology Group, Laboratory Branch, Technical Services Division, U.S.D.A., dated

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July 31, 1970, and by a number of publications authored by experts in the fields of microbacteriology and food science. (See, Documentary Record of Rule Making Proceedings, filed January 8, 1971).

On the basis of the above record and in view of the fact that the regulation in question presents questions of a technical nature which are properly within the expertise of the administrative agency, this court concludes that there was rational basis for 9 C.F.R. 318.7(d)(2).

Assuming this court would be required to conduct an evidentiary hearing de novo on the question whether there was a rational basis for the promulgation of 9 C.F.R. 318.7(d)(2), the affidavits of Vaughn and York filed by plaintiffs (filed as an exhibit to plaintiffs' supporting memorandum January 28, 1971) fail to raise a genuine issue of fact as to the principal ground upon which the regulation was promulgated, i.e., that sorbates and sorbic acid retard the growth of mold and other surface growth in meat products and thereby mislead the consumer in making the product appear better than it actually is.

The affidavit of Vaughn, supra, does no deny or even cast doubt on that point. It merely challenges another, separate ground upon which the regulation was based, i.e., that sorbates are also a medium for the growth in meats of clostridia—a cause of food poisoning.

The affidavit of York, supra, while similarly challenging this last mentioned ground, does not challenge the fact that sorbates and sorbic acid retard the

growth of molds and other surface growth in meat products while subsurface bacterial spoilage is occurring and thereby mislead the consumer by causing the product to appear better than it actually is. In fact, York admits that sorbates do just that when he states: "Therefore, sorbic acid may be effective in cooked sausage in retarding mold and yeast growth but not against bacterial spoilage." (Affidavit of York filed as an exhibit to plaintiffs' supporting memorandum January 28, 1971, at p. 4).

Moreover, the affidavit of York (at p. 6) recites that he has no objections to statements 5 and 6 contained in an affidavit of Ralph W. Johnston (Attached as an exhibit to defendants' supporting memorandum, filed January 4, 1971) submitted by defendants wherein Johnston stated that: "Sorbic acid and its salts inhibit the growth of fungi such as mold and yeast . . . "and that" . . . they also inhibit the growth of some but not all species of bacteria."

It should also be noted that Vaughn and York, although authors of one of the quoted professional articles appearing in the documentary record of the rule-making proceedings, were but two of several authorities relied upon by the Secretary of Agriculture in finding his basis for 9 C.F.R. 318.7(d)(2).

From the affidavits of Vaughn and York, submitted by plaintiffs, and the affidavit of Johnston, submitted by defendants, as well as the documentary record of the rule-making proceedings, it appears that there is no genuine issue as to the following material fact, i.e., that sorbic acid and sorbates prevent the growth of

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mold and other surface growths in meat products, such as cooked sausages, while not inhibiting certain bacterial subsurface spoilage and thus make meat products appear better than they actually are, thereby misleading the consumer.

It follows, therefore, that, even assuming there could be dispute about the Secretary's second ground for his regulation, the undisputed first ground would alone constitute a rational basis for 9 C.F.R. 318.7(d)(2).

Having found that regulation 9 C.F.R. 318.7(d)(2) is both procedurally and substantively valid, this court is of the opinion that U.S.D.A. is authorized to disapprove labels which declare the presence of the prohibited additives because the use of the prohibited additives would render the products "adulterated" within the meaning of the Federal Meat Inspection Act, 21 U.S.C. 601(m)(2)(C). The Federal Meat Inspection Act, as amended, in 21 U.S.C. 604, 606, charges U.S.D.A. with the responsibility of ascertaining that products to which the official inspection legend is affixed are not "adulterated." The disapproval of labels bearing additives which would render the product "adulterated" is, therefore, a lawful exercise of the functions of U.S.D.A.

For the reasons above set forth it is ordered that plaintiffs' motion for summary judgment should be, and the same is hereby, denied; and defendants' motion for summary judgment should be, and the same is hereby, granted, insofar as it seeks a declaratory judgment that regulation 9 C.F.R. 318.7(d)(2) is a

valid and enforceable regulation of the Secretary of Agriculture and that the practice of disapproving labels as admitted by defendants is a lawful exercise of its functions under the Federal Meat Inspection Act, as amended.

Dated: October 20, 1971.

/s/ W. T. Sweigert
W. T. Sweigert
United States District Judge

Appendix C

REPORTER'S TRANSCRIPT, UNITED STATES DISTRICT COURT

Friday, November 19, 1971

The Clerk: Number seven on the calendar.

Civil Action 49834, Chip Steak v. Clifford Hardin, plaintiff's motion to amend findings.

Will counsel please state their appearances for the record?

Mr. McKray: George McKray for Chip Steak Company.

Mr. Denton: Brian Denton for the government.

The Court: Well, here we are again.

This has to do with your request that I amend my last memorandum decision in this matter, Mr. McKray, to suit you, isn't that correct?

Mr. McKray: No. To follow the law.

The Court: That's a good response.

Well, I think what you better do now is to take an appeal.

Mr. McKray: I beg your pardon?

The Court: Take an appeal, you see. I think we have considered it very thoroughly, and——

Mr. McKray: Can I ask one question?

The Court: Yes.

Mr. McKray: The question on, there is no administrative record.

The Court: On what?

Mr. McKray: There is no administrative record in this case. The cutoff was in December of 1969. The government's evidence, or documents came in in July of 1970.

The Court: I don't know what you are talking about.

Mr. Denton: Mr. McKray is arguing his case again, Your Honor.

Mr. McKray: No, Your Honor. It's all in my memorandum, but I don't believe you read my memorandum.

The Court: No, frankly, I haven't.

Mr. McKray: All right.

Mr. Denton: Your Honor——

The Court: But I put an awful lot of time into my memorandum, I will tell you that.

Mr. McKray: I realize that.

The Court: Motion denied.

Mr. Denton: Your Honor, I have a proposed form of order.

Mr. McKray: Yes.

Mr. Denton: Thank you, Your Honor.

Appendix D

United States Court of Appeals
For The Ninth Circuit

Chip Steak Co., Inc., Vao L. Cheney, Miller Packing Co., Frank De Benedetti, and Western States Meat Packers Association, L. Blaine Liljenquist,
Appellants,

vs.

Clifford Hardin, Secretary of Agriculture, J. C. Leighty, Director of Technical Service Division, M. E. Christopherson, Director of Western Meat Inspection,
Appellees.

No. 72-1212

[October 31, 1972]

Appeal from the United States District Court
for the Northern District of California

Before: ELY and GOODWIN, Circuit Judges, and FERGUSON, District Judge.*

PER CURIAM:

A meat processor sought injunctive and declaratory relief in the district court against enforcement of a United States Department of Agriculture regulation which proscribes the addition of sorbic acid to proc-

*The Honorable Warren J. Ferguson, United States District Judge for the Central District of California, sitting by designation.

essed meat products. From a summary judgment in favor of the Secretary of Agriculture, the processor appeals.

The district court decision is reported in *Chip Steak Co. v. Hardin,* 332 F. Supp. 1084 (N.D. Cal. 1971). The district court's careful and comprehensive memorandum opinion fully states the law and the facts.

The challenged U.S.D.A. regulation, found at 9 C.F.R. § 318.7(d)(2), was adopted pursuant to the Federal Meat Inspection Act of 1907, 34 Stat. 1260, as amended by the Wholesome Meat Act of 1967, Pub. L. 90-201, 81 Stat. 584, 21 U.S.C. § 601, et seq. (Supp. 1971). The regulation provides:

> "(d) No substance may be used in or on any product if it conceals damage or inferiority or makes the product appear to be better or of greater value than it is. Therefore:
>
> " * * * * * *
>
> "(2) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid may not be used in cooked sausage or any other product * * *."

Chip Steak attacks the regulation on a variety of procedural grounds. We agree with the district court that the asserted deficiencies in the department's rule-making procedure afford no basis for attacking the regulation.

Affirmed.

Appendix E

No. 72-1212

United States Court of Appeals

For the Ninth Circuit

CHIP STEAK CO., INC., VAO L. CHENEY, MILLER PACKING CO., FRANK DE BENEDETTI, and WESTERN STATES MEAT PACKERS ASSOCIATION, L. BLAINE LILJENQUIST,

Appellants,

vs.

CARL L. BUTZ, SECRETARY OF AGRICULTURE, J. C. LEIGHTY, DIRECTOR OF TECHNICAL SERVICE DIVISION, M. E. CHRISTOPHERSON, DIRECTOR OF WESTERN MEAT INSPECTION,

Appellees.

Appeal from the United States District Court for the Northern District of California

APPELLANTS' PETITION FOR A REHEARING

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Subject Index

I

Page

his court and the district court failed to determine whether the Secretary of Agriculture is authorized to approve chemical substances for use in the preparation of meat products without regard for the Federal Food Additive Amendment 2

II

rehearing on this issue requires consideration of three questions 4

1. Whether regulations 9 C.F.R. 318.7(a)(1)(2) and (c) are unconstitutional and void because the Secretary of Agriculture lacks the statutory authority to approve food additives for use in meat products under 21 U.S.C. 601(m)(2)(D) 5

2. Whether the Secretary of Agriculture can bypass 21 U.S.C. 601(m)(2)(C) and (D) and ban food additives which have been approved by the Secretary of Health, Education and Welfare by the device of disapproving individual labels declaring the presence of such food additives 5

3. Whether the Secretary of Agriculture's promulgation of regulations prohibiting or restricting food additives in meat products must be accomplished in accordance with specific statutory procedures required by 21 U.S.C. 348(h) 6

Table of Authorities Cited

House Reports

Pages

House Report, No. 92-1338 on "Regulation of Food Additives—Nitrite and Nitrate" by the Committee on Government Operations (92 Cong. 2d Sess., August 15, 1972) .. 6

Regulations

9 C.F.R.:

No. 318.7(a) 5

No. 318.7(a)(1) 3, 5

No. 318.7(a)(2) 3, 5

No. 318.7(c) 5

No. 318.7(d)(2) 4

Statutes

Federal Meat Inspection Act:

21 U.S.C. 601 (m) (2) (C) 2, 5, 6

21 U.S.C. 601 (m) (2) (D) 2, 5, 6

Food Additive Amendment:

21 U.S.C. 348 ..... 2, 3, 5, 6, 7

21 U.S.C. 348(h) 6

No. 72-1212

United States Court of Appeals

For the Ninth Circuit

CHIP STEAK CO., INC., VAO L. CHENLY, MILLER PACKING CO., FRANK DE BENEDETTI, and WESTERN STATES MEAT PACKERS ASSOCIATION, L. BLAINE LILJENQUIST,

Appellants,

vs.

CARL L. BUTZ, SECRETARY OF AGRICULTURE, J. C. LEIGHTY, DIRECTOR OF TECHNICAL SERVICE DIVISION, M. E. CHRISTOPHERSON, DIRECTOR OF WESTERN MEAT INSPECTION,

Appellees.

Appeal from the United States District Court for the Northern District of California

APPELLANTS' PETITION FOR A REHEARING

To the Honorable Walter Ely and Alfred T. Goodwin, Circuit Judges and Warren J. Ferguson, District Judge:

Appellants respectfully petition this Court to grant a rehearing on the ground that neither the District Court nor this Court have reached a determination upon the primary issues raised in this action.

I

THIS COURT AND THE DISTRICT COURT FAILED TO DETERMINE WHETHER THE SECRETARY OF AGRICULTURE IS AUTHORIZED TO APPROVE CHEMICAL SUBSTANCES FOR USE IN THE PREPARATION OF MEAT PRODUCTS WITHOUT REGARD FOR THE FEDERAL FOOD ADDITIVE AMENDMENT.

The authority of the Secretary of Agriculture to regulate food additives in meat products is derived from one provision of the Federal Meat Inspection Act (21 U.S.C. 601 (m) (2) (C) and (D):

> "(m) The term 'adulterated' shall apply to any . . . meat food product under one or more of the following circumstances . . .
>
> (2) (C) if it bears or contains any food additive which is unsafe within the meaning of Section 348 [Food Additive Amendment administered by the Secretary of H.E.W.] of this title.
>
> (D) *Provided,* that an article which is not adulterated under Clause (B), (C) or (D) shall nevertheless be deemed adulterated if the use of the pesticide chemical, food additive, or color fixative in or on such article is *prohibited by regulations of the Secretary* [*of Agriculture*] in this subchapter." (Emphasis added)

Appellants contended in their amended complaint filed in the District Court that despite this statutory provision limiting the authority of the Secretary of Agriculture to prohibiting the use of food additives in meat products by means of promulgating regula-

tions, the Secretary had in fact adopted the practice of approving and disapproving additives without regard to the federal Food Additive Amendment. (R. 9) Appellees admitted this contention in their answer. (R. 18)

The Secretary's conduct respecting food additives in meat products was thereafter formalized by his promulgation of final regulations in October 1970, which permitted him to approve chemical substances without regard to the federal Food Additive Amendment,

> "No chemical substance may be used in the preparation of any [meat] products unless it is *approved* in this part of Part 319 of this subchapter *or by the Administrator in specific cases.*" (9 C.F.R. 318.7(a)(1), emphasis added.)
>
> "No product shall bear or contain any substance which would render it adulterated or which is not *approved* in this part of Part 319 of this subchapter *or by the Administrator in specific cases.*" (9 C.F.R. 318.7(a)(2), emphasis added.)

Appellants challenged these regulations in the District Court proceedings (R. 37-39) on the ground that while they permitted additives to be *approved* by the Secretary of Agriculture without regard to the federal Food Additive Amendment, the provision of the Federal Meat Inspection Act granting authority to the Secretary merely permitted additives to be "prohibited by regulations of the Secretary." This issue was argued in appellant's memorandum supporting their motion for summary judgment. (R. 100, 105-110)

The issue was ignored in the decision of the District Court, whose written opinion merely discussed appellants' contentions relating to a regulation, 9 C.F.R. 318.7(d)(2), prohibiting the use of sorbates in cooked sausage. Appellants' motion to amend the District Court's findings and order (R. 171) to include a determination of this issue (R. 172-174) was denied (R. 181).

Appellants then raised the issue in their opening brief before this Court as the primary contention on appeal. (Appellants' Opening Brief 1, 9.) Appellees responded with considerable discussion in their reply brief (Appellees' Reply Brief 14-24). Yet the decision of this Court, as that of the District Court, failed even to mention the merits of the issue. A determination of this important issue thus necessitates the granting of this petition for rehearing.

II

A REHEARING ON THIS ISSUE REQUIRES CONSIDERATION OF THREE QUESTIONS

The issue of the Secretary's authority to approve chemical substances was discussed by appellants and appellees in their briefs before this Court in terms of the following questions:

1. **Whether regulations 9 C.F.R. 318.7(a)(1)(2) and (c) are unconstitutional and void because the Secretary of Agriculture lacks the statutory authority to approve food additives for use in meat products under 21 U.S.C. 601(m)(2)(D).**

Appellants argued that the Secretary of Health, Education and Welfare and of Agriculture have concurrent jurisdiction over food additives in meat products (Reply Brief for Appellants, pages 6-7), and that the Secretary of Agriculture can only prohibit or restrict food additives already approved by HEW from being improperly used in meat products (Opening Brief for Appellants, pages 9-11). Appellees argued that the Secretary of Agriculture has independent jurisdiction to approve food additives in meat products (Brief for Appellees, pages 9-13).

2. **Whether the Secretary of Agriculture can bypass 21 U.S.C. 601(m)(2)(C) and (D) and ban food additives which have been approved by the Secretary of Health, Education and Welfare by the device of disapproving individual labels declaring the presence of such food additives.**

Appellees argued that the Secretary of Agriculture's present actions are a reaffirmation of his long-standing rule existing prior to the passage of the 1958 Food Additive Amendment. This rule prohibits the use of all substances in the preparation of meat products at federally-inspected plants unless such use is specifically permitted by the Secretary, whether or not regulations regarding these substances are in effect. (9 C.F.R. 318.7(a)) (Brief for Appellees, pages 3, 16-21) Appellants replied that this long-standing rule is in direct conflict with the present law. (Reply Brief for Appellant, pages 5-7)

3. Whether the Secretary of Agriculture's promulgation of regulations prohibiting or restricting food additives in meat products must be accomplished in accordance with specific statutory procedures required by 21 U.S.C. 348(h).

Appellees argued that the Secretary of Agriculture has independent jurisdiction and quoted the District Court opinion (R. 161-162) stating that the Federal Meat Inspection Act contains no expressed procedures for rule-making by the Secretary of Agriculture. (Brief for Appellees, pages 34-37) Appellants argued that the Federal Meat Inspection Act as amended does not provide special procedures for rule-making because all regulations regarding food additives are to be promulgated according to the procedures of the Food Additive Amendment, 21 U.S.C. 348. (Opening Brief for Appellants, pages 11-15)[1]

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[1]It should be noted that a recent House Report, No. 92-1338 on "Regulation of Food Additives—Nitrite and Nitrate" by the Committee on Government Operations (92 Cong. 2d Sess., August 15, 1972), examined the administration of the federal Food, Drug and Cosmetic Act by HEW's Food and Drug Administration (FDA) and the Wholesome Meat and Poultry Acts by USDA's Animal and Plant Health Inspection Service (APHIS) in regulating food additives.

The report, on page 3, gives the congresional history as follows:

> ". . . [Congressional action] ultimately resulted in the passage of the Food Additive Amendment of 1958 requiring FDA preclearance of all new food additives before marketing. "Since then Congress has enacted three laws governing the wholesomeness and safety of foods which have incorporated the protective coverage of the Food Additive Amendment. These are the Wholesome Meat Act. . . ."

The report, on page 6, gives the legal responsibilities of FDA and APHIS regarding food additives as follows:

> "FDA has the responsibility for determining the safety of all food additives, and for publishing regulations approving additive uses and establishing limitations on the amounts of additives that may be used for given purposes. FDA also has the responsibility to monitor the Nation's food supply, with the exception of meat, poultry and egg products, to assure the safety of food additive uses. This involves the

This Court did not resolve these issues left unresolved by the District Court. There has thus been no determination as to whether the Secretary of Agriculture can approve or disapprove chemical substances for use in meat products without regard for the federal Food Additive Amendment.

Dated, San Francisco, California,
November 13, 1972.

Respectfully submitted,
GEORGE A. MCKRAY,
Attorney for Appellants and Petitioners.

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inspection of establishments and the sampling and analysis of marketed foods to determine the quantity of additives present.

"While *FDA must evaluate food additives for use in meat*, poultry and egg products, APHIS has the responsibility for enforcing quantitative restrictions and proper use of additives in these products. APHIS exercises this responsibility through the continuous inspection of meat, poultry, and egg products establishments." [Emphasis added]

The congressional report was based upon public hearings in which there was active participation by both the FDA and the USDA. The report found that at times these agencies made specific decisions which were not in accordance with the law and the scientific evidence on food additives (supra, pages 20-26). The report recommended that the Commissioner of the Food and Drug Administration and the Secretary of Agriculture promptly review the policies and procedures of their respective agencies for the regulations of chemical preservatives (nitrite and nitrate) in food and take such steps as necessary to correct the deficiencies disclosed in this report (supra, pages 26-27).

Appendix F

United States Court of Appeals
for the Ninth Circuit

Chip Steak Co., Inc., et al., Appellants, vs. Clifford Hardin, Secretary of Agriculture, et al., Appellees.	No. 72-1212

[November 28, 1972]

Appeal from the United States District Court
for the Northern District of California

Before: ELY and GOODWIN, Circuit Judges, and FERGUSON, District Judge.*

ORDER

Appellants' petition for rehearing, filed November 14, 1972, is

DENIED.

*The Honorable Warren J. Ferguson, United States District Judge for the Central District of California, sitting by designation.

Appendix G

TEXT OF RELEVANT STATUTES AND REGULATIONS

STATUTORY PROVISIONS

Meat Inspection Act as amended by the Wholesome Meat Act of 1967 (Chapter 12—Meat Inspection)

Section 1(m)(2)(C), (D) [21 USC 601(m)(2)(C), (D)]:

> (m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:
>
> (2) (C) if it bears or contains any food additive which is unsafe within the meaning of section 348 [Food Additive Amendment] of this title,
>
> (D) if it bears or contains any color additive which is unsafe within the meaning of section 376 of this title. *Provided,* That an article which is not adulterated under Clause (B), (C) or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter;

Section 1(m)(8) [21 USC 601(m)(8)]:

> (m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom, or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength; or make it appear better or of greater value than it is;

Federal Food, Drug and Cosmetic Act (Chapter 9—Federal Food, Drug and Cosmetic Act)

Section 402(b) [21 USC 342(b)]:

A food shall be deemed to be adulterated—

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Food Additive Amendment of 1958 (Chapter 9—Federal Food, Drug and Cosmetic Act)

Section 409(h) [21 USC 348(h)]:

The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedures shall conform to the procedure provided in this section [Food Additive Amendment] for the promulgation of such regulations.

REGULATIONS

9 CFR 318.7

(a)(1) No chemical substance may be used in the preparation of any product unless it is approved in this part or Part 319 of this subchapter or by the Administrator in specific cases.

(2) No product shall bear or contain any substance which would render it adulterated or which is not approved in this part or Part 319 of this subchapter or by the Administrator in specific cases.

(c) Under appropriate declaration as required in Parts 316 and 317 of this subchapter, the following substances may be added to products . . .

(d) No substance may be used in or on any product if it conceals damage or inferiority or makes the product appear to be better or of greater value than it is. Therefore: . . .

(2) Sorbic acid, calcium sorbate, sodium sorbate and other salts of sorbic acid may not be used in cooked sausage or any other product; . . . except that potassium sorbate, propylparaben (propyl p-hydroxybenzoate), calcium propionate, sodium propionate, benzoic acid and sodium benzoate may be used in or on any product only as provided in the chart in §318.7(c)(4) or as approved by the Administrator in specific cases.